

REMARKS

By this amendment claims 1-41 and 51-56 are pending in this application. Claims 42-50 are hereby cancelled without prejudice or disclaimer. By the present amendment, claim 7 is amended not for patentability, but rather, because upon review of the claims, Applicants realized that it is mathematically impossible for the sterol ester composition of the present invention to have more than 50% monounsaturated fatty acid moieties as well as 50% polyunsaturated fatty acid moieties. Claims 1, 4, and 7 are amended for clarification. Support for the modification to claim 1 is found in the specification on page 5, line 9. Support for the modification to claim 4 is found in the specification on page 5, lines 11-12. Support for the modification to claim 7 is found in the specification on page 4, line 21.

In view of the above amendments and the following remarks, reconsideration of claims 1-41, and 51-56 is respectfully requested.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 51-56 are rejected under 35 U.S.C. § 112, second paragraph as indefinite for reciting “a free sterol level of less than 10%” in claim 51. MPEP § 2173.02 states that definiteness of claim language must be analyzed in light of the content of the particular application disclosure, among other things. Page 4, line 4 of the specification defines “free sterols” as “unesterified sterols.” Accordingly, the claim terminology “a free sterol level of less than 10%” is readily understood in light of the specification and is definite within § 112, second paragraph. *maintains*

1-40 and 51-56 are rejected under 35 U.S.C. § 112, second paragraph as using trademarks or tradenames, namely MUFAs, SFAs, and PUFAs, to identify particular materials. As set forth in the specification, these are abbreviations for the names of particular types of fatty acids, rather than trademarks or tradenames. MUFAs are monounsaturated fatty acids (specification, p. 5, l. 9), SFAs are saturated fatty acids (p. 5, l. 11-12), and PUFAs are polyunsaturated fatty acids (specification, p. 4, l. 21). Claim 1, 4, and 7 have been amended to recite the names of these fatty acids along with the acronyms to clarify that these are merely abbreviations and not trademarks or tradenames.

Claim rejections under 35 U.S.C. § 103(a)

Claims 1-41 and 51-56 are rejected under 35 U.S.C. § 103(a) as unpatentable over Miettinen *et al.* (US Pat. No. 5,502,045; hereinafter "Miettinen") and Wester *et al.* (WO 99/56558, hereinafter "Wester") in view of Letton *et al.* (US Pat. No. 5,306,516, hereinafter "Letton") and Dickson (US Pat. No. 5,869,304, hereinafter "Dickson").

Claims 1 and 41 are the only independent claims, all others depend thereon. Claim 1 recites a sterol ester composition wherein more than 50% of the fatty acid moieties are monounsaturated fatty acids (MUFAs). Claim 41 recites a salad or cooking oil that is free of solids at temperatures greater than about 60° F and that comprises more than about 10% sterol esters.

Neither Miettinen nor Wester teach or suggest a sterol ester composition wherein more than 50% of the fatty acid moieties are MUFAs. Miettinen teaches a new method for producing β -sitostanol fatty acid esters. Miettinen, however, does not teach or suggest that using more than 50% monounsaturated fatty acids with in the production of β -sitostanol fatty acid esters, or any other sterol or stanol fatty acid ester, will produce sterol ester compositions suitable for use in food applications wherein taste and texture effectively limit the suitability of possible sterol/stanol fatty acid ester compositions (see, e.g. p. 3, l. 29-30 of the instant application).

Wester teaches sterol/stanol fatty acid esters comprising more than 50% polyunsaturated fatty acids (PUFAs). Page 5 of Wester explains that the sterol/stanol fatty acid esters should comprise more than 50% PUFAs in order to avoid having a texturizing effect. (See Wester, p. 5 first full paragraph). Wester goes on to show that the melting properties of sterol/stanol fatty acid esters with a relatively higher MUFA content, prepared from low erucic acid rapeseed oil, as in Miettinen, have unsatisfactory melting properties, (Wester, page 5, l. 14-17), while sterol/stanol fatty acid esters prepared with high PUFA oils have good melting properties (Wester, p. 5, l. 25-26). Furthermore, Wester teaches that while these sterols/stanols are effective in reducing the absorption of cholesterol, using commercially available high PUFA vegetable oils to produce the sterol/stanol fatty acid esters results in texturizing properties that are too poor for the resulting sterol/stanol fatty acid esters to be used in food applications in optimal levels for effective reduction of cholesterol absorption (Wester, p. 3, l. 34 to p. 4, l. 2).

Wester then teaches that by further increasing the content of PUFAs compared to natural high PUFA liquid vegetable oils yields even better results, i.e. higher levels of the sterol/stanol fatty acid ester can be incorporated into foods than when sterol/stanol fatty acid esters with lower PUFA contents are used (Wester, p. 7, l. 20-25).

Accordingly, upon reading Miettinen and Wester, there would be no motivation to use a higher content of MUFAs than PUFAs in sterol/stanol fatty acid ester compositions. Rather, Wester teaches not only that the oil chosen for sterol/stanol esterification should have a high PUFA content, but that the PUFA content should be higher than that of naturally occurring high PUFA oils. Reading Wester it would not make sense to produce a sterol ester composition having more than 50% MUFA content because the resulting sterol esters would be expected to have undesirable textural qualities when added to foods at levels effective for reducing cholesterol absorption, thus making the resulting sterol ester composition unsuitable for its intended purpose.

The Examiner then cites Letton as providing motivation for preparing sterol esters with more than 50% MUFAs. Letton teaches that in the production of polyol fatty acid polyesters, and shortening compositions comprising polyol fatty acid polyester compositions, it is preferred to use mono- or diunsaturated fatty acids for better oxidative stability. Letton does not suggest, however, that mono- or di-unsaturated fatty acids will provide oxidative stability for sterol ester compositions. ✓

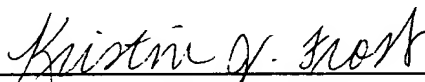
Letton is also cited for the proposition that “fatty acid moieties including unsaturated and saturated can be used broadly in mixture with each other in all proportions in a composition to achieve desirable physical properties.” On page 5, lines 44-46 and 51-55, Letton teaches that of the preferred fatty acids in groups (a) and (b), which consist of monounsaturated, diunsaturated, polyunsaturated, and saturated fatty acids, the fatty acids can be added in almost any combination. However, Letton is again using these fatty acids in polyol fatty acid polyesters, which are different from the sterol/stanol esters of the present invention. Read in light of Wester, which teaches that high PUFA content is necessary in order to have desirable textural properties at effective sterol/stanol levels, it is clear that unsaturated and saturated fatty acids cannot be used in any combination and still get a product that is satisfactory for its intended purpose.

Finally, Dickson is cited for the proposition that diets rich in SFAs are associated with increased risk of coronary artery disease whereas MUFAs are associated with decreased risk. Dickson does not teach or suggest the esterification of plant sterols/stanols at all, much less using a high MUFA content for the esterification of plant sterols/stanols. Dickson, rather, discloses a method for specifying a particular fatty acid at the sn2 position of acylglycerol lipids by transfecting a vector containing a gene that will allow a host plant that is useful in oil production to have a specified oil at the sn2 position. Again, read in light of Wester, there would be no reasonable expectation that a satisfactory product can be produced when more than 50% of the fatty acid moieties are MUFAs.

In view of the above amendments and remarks, it is submitted that claims 1-41 and 51-56 are now in condition for allowance. Prompt notice of such allowance is respectfully requested.

Respectfully submitted,

Date: July 29, 2002

A handwritten signature in cursive script, reading "Kristin J. Frost", is written over a horizontal line.

Kristin J. Frost
Reg. No. 50,627
216/622-8895

MARKED-UP VERSION OF THE CLAIMS

1. (Amended) A sterol ester composition, wherein more than 50% of the fatty acid moieties are monounsaturated fatty acids (MUFAs).
4. (Amended) The sterol ester composition of claim 1, wherein less than about 6% of the fatty acid moieties are saturated fatty acids (SFAs).
7. (Amended) The sterol ester composition of claim 6, wherein [50% or] less than 50% of the fatty acid moieties are polyunsaturated fatty acids (PUFAs).